Questionnaire 8 Exemption 14 of RoHS Annex IV

Lead in single crystal piezoelectric materials for ultrasonic transducers

Acronyms and Definitions

US	ultrasonic
SC	Single crystal

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

You submitted information to substantiate your request for the renewal of the above-mentioned exemption. This information was reviewed and as a result, we ask you to kindly answer the below questions for further clarification of your request until 9 September 2021.

2. Questions

1) We had asked you to provide examples of handheld US devices which use transduers based on single crystal PZT material. You provided examples of PZT transducers based on polycrystaline PZT

   These transducers would not be covered by exemption IV-14 but by exemption III-7(c)(I), and thus are not an example of single crystal PZT material being used in handheld US systems. In other such devices, e.g. the Butterfly Network system, cMUT transducers are applied. We therefore propose to exclude handheld devices from the scope of exemption 14 with the below wording:

   Lead in single crystal piezoelectric materials for ultrasonic transducers in medical ultrasonic systems other than handheld ones.

   Would you please comment on this?

   COCIR does **not** agree with the proposed wording. It is not appropriate to potentially limit the performance of handheld devices by banning Single Crystal (SC) materials for these types of US device. There is no accepted definition of handheld and so COCIR cannot confirm that there are no single crystal transducers used in handheld devices, in fact it appears that there are some SC handheld products already on the market. Furthermore, it does not mean than more SC handheld will not be developed and used in the future to provide enhanced diagnostic imaging and performance, in fact this is very likely to occur due to growing future medical requirement. If handheld devices can continue to make advances using better technology this will include Single Crystal and this would allow for handheld devices to replace larger, non-portable (or less easily portable) systems for more difficult patient diagnoses. This would in turn

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

save wider scale resources (i.e. power, conflict minerals, precious metals, etc…) much more efficiently, and on a much larger general scale, than a restriction of Single Crystal for this class of devices. Such proposal will severely discourage US companies from developing Single Crystal transducers on handheld device, which is not good for patients or diagnostic healthcare.

In addition there is currently no clear and consistent definition of "handheld" and "portable" even within COCIR members who each have their own, different, meanings of these terms. For example, the question if catheters would be considered as a handheld US system, was raised but cannot be answered.

Again, cMUT and/or pMUT technology may never offer the image quality performance achieved by SC US, even in a handheld device, than more conventional transducer technology can offer.

Many COCIR members are currently developing single crystal devices that might be regarded as "handheld" or "portable" (depending on definition). Some are already available. These will give superior image quality to polycrystalline PZT and to cMUT and pMUT due to the technical performance reasons explained in our exemption renewal request. Note that most single crystal transducers usually do not use PZT, but use the other lead compounds that are described in our exemption renewal request.

2) Small feature sizes are one strength of cMUT systems which may also play a role in portable devices (classification as used in Philips (2018).

   Are single crystal PZT materials used in portable US systems? If so, could you kindly give us some examples?

There is no accepted standard definition of the term 'portable devices'. Some devices can be hand carried, but larger ones can be moved on trolleys. If by portable devices it is meant to refer to systems in the same category as the Philips CX50 US system, then examples of single crystal material transducers used are as follows:

- Mindray SP5-1s on M9 portable uses single crystal for better penetration and resolution[2]
- Siemens: transducer on Bonsai US system
- Philips: S5-1, C10-3v, and X7-2t on CX50 US system
- GE: Vivid-IQ with the M5Sc cardiac probe

If the reference to 'small feature sizes' means the size of the transducer, then the size of transducer is decided by the clinical application/human hands (to hold the device), not by the materials used. Actually, for a given clinical application, the size of cMUT transducers is the same as ceramic polycrystalline and single crystal transducers.

If by "small feature sizes" it is meant the small "element" size which cannot be manufactured with the traditional dicing process, this has been previously answered.

3) Catheters are another application which may play to the strengths of cMUT and/or pMUT.
   a) Are single crystal PZT transducers used in catheters? If so, please kindly provide product examples.
   b) If not, please let us know which alternative materials/techniques are used.

COCIR members currently manufacture catheters using polycrystalline PZT (not single crystal). It is unclear whether catheters would be regarded as "handheld" as there is no accepted standard definition of this word. One US manufacturer makes one single crystal PZT catheter

[2] https://www.mindrayuk.com/solutions/m9/

(ICE/VeriSight), but this device is approved for use only in the USA, however several COCIR members are developing SC catheter products.

The use of catheter based procedures is rapidly progressing and will be driven to replace more invasive, transesophageal echocardiography (TEE) imaging of heart structural procedures. In order to keep pace with the projected demands for improved image quality associated with the advancing requirements of non-TEE based procedures and single crystal may be called upon as a solution. Again, this is a similar issue to the “handheld” device not having legislative limitations imposed on new designs. There will be medical patient benefits from use of new superior-performance medical devices (handheld or otherwise) as well as there being overall resources saved (by switching to new smaller devices). Also, by use of superior performance equipment the use of less invasive procedures, becomes possible as well a sless resource intensive treatment methods if open surgery can be replaced by less invasive techniques..

Artificially limiting the ability to improve imaging performance (of hand-held or portable) by imposing restrictions on an important material such as single crystal that is being used in emerging medical applications that can vastly improve patient outcomes, as well as significantly reduce resource consumption, should not be implemented.

Please note that answers to these questions may be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.

It would be helpful if you could kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.

3. References

Philips (2018): CMUT and PMUT: New Technology Platform for Medical Ultrasound. Unter Mitarbeit von Rob van Schaijk, Philips Innovation Services, MEMS & Micro Devices. Online verfügbar unter https://www.engineeringsolutions.philips.com/app/uploads/2019/03/CMUT-and-PMUT-Rob-van-Schaijk-November-2018.pdf.